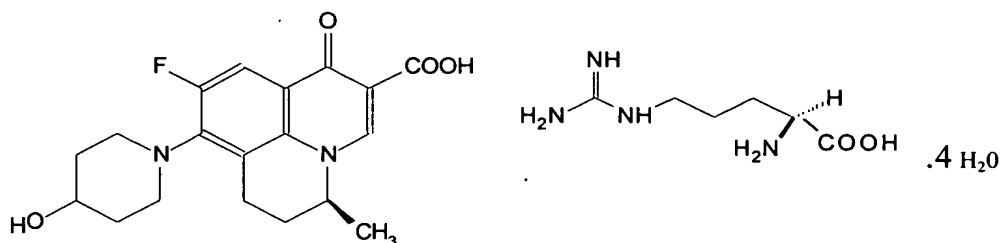


## CLAIMS

1. S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j] quinolizine-2-carboxylic acid L-arginine salt tetrahydrate of the formula I



Formula I

in a crystalline form.

2. A S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j] quinolizine-2-carboxylic acid L-arginine salt tetrahydrate having the following X-ray powder diffraction data:  $(2\theta): 4.86 \pm 0.2, 14.10 \pm 0.2, 14.90 \pm 0.2, 19.35 \pm 0.2, 22.20 \pm 0.2, 23.04 \pm 0.2, 23.54 \pm 0.2, 28.44 \pm 0.2, 39.44 \pm 0.2$ .
3. A S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate having the following X-ray powder diffraction data:  $(2\theta): 4.86 \pm 0.2, 14.10 \pm 0.2, 14.90 \pm 0.2, 19.35 \pm 0.2, 22.20 \pm 0.2, 23.04 \pm 0.2, 23.54 \pm 0.2, 28.44 \pm 0.2, 39.44 \pm 0.2$ ; a DSC exotherm at  $194.93^\circ\text{C}$  (onset at  $189.42^\circ\text{C}$ ) and one endotherm at  $87.83^\circ\text{C}$ ,  $144.03^\circ\text{C}$  and  $251.26^\circ\text{C}$  and a water content of between 11.0 to 12.5% by weight as determined by titration according to Karl Fischer.
4. The S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2, having a DSC exotherm at  $194.93^\circ\text{C}$  (onset at  $189.42^\circ\text{C}$ ) and one endotherm at  $87.83^\circ\text{C}$ ,  $144.03^\circ\text{C}$  and  $251.26^\circ\text{C}$ .
5. The S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2, wherein the solubility in a solution of pH 9.5 is 5.0 mg/ml.
6. The S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j] quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 3, wherein the solubility in a solution of pH 9.5 is 5.0 mg/ml.
7. The S-(-)-9- fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according

to claim 1, wherein the water content is between 11.0 % and 12.5 % by weight as determined by titration according to Karl Fischer.

8. The S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2, wherein the water content is between 11.0 % and 12.5 % by weight as determined by titration according to Karl Fischer.

9. A process for the manufacture of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate comprising the steps of:

- a) heating a suspension of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H, 5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate in an organic solvent and water at 70-80°C to obtain a clear solution;
- b) cooling the solution to provide a crystalline substance;
- c) isolating the crystalline form of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H, 5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate tetrahydrate at 30°C - 35°C by filtration or centrifugation;
- d) air drying of the crystalline form of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j] quinolizine-2-carboxylic acid L-arginine salt tetrahydrate tetrahydrate at a temperature between 30°C - 35°C.

10. A process according to claim 9, wherein the organic solvent is acetone or acetonitrile.

11. The process according to claim 9 wherein the organic solvent is acetone.

12. A composition comprising S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 1 and a carrier, diluent, solvent or excipient.

13. A composition comprising S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2 and a carrier, diluent, solvent or excipient.

14. A composition comprising S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate tetrahydrate according to claim 3 and a carrier, diluent, solvent

or excipient.

15. A method for treating a disease caused by a microbial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 1 to the mammal in need thereof.

16. A method for treating a disease caused by a microbial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2 to the mammal in need thereof.

17. A method for treating a disease caused by a microbial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 3 to the mammal in need thereof.

18. A method for preventing a disease caused by a microbial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 1 to the mammal at risk of being infected.

19. A method for preventing a disease caused by a microbial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2 to the mammal at risk of being infected.

20. A method for preventing a disease caused by a microbial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 3 to the mammal at risk of being infected.